[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed collection; comment request (60-Day FRN); The Clinical Trials Reporting Program (CTRP) Database (NCI)

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) The quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology. To submit comments in writing, request more information on the proposed project, or to obtain a copy of the data collection plans and instruments, contact: Jose Galvez, Office of the Director, National Cancer Institute, 2115 East

Jefferson Street, Rockville, MD 20852 or call non-toll-free number 301-443-6141 or E-mail your request, including your address to: jose.galvez@nih.gov.

Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

PROPOSED COLLECTION: The Clinical Trials Reporting Program (CTRP) Database, 0925-0600, Expiration Date 3/31/2013 – EXTENSION, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: The Clinical Trials Reporting Program (CTRP) is an electronic resource that serves as a single, definitive source of information about all NCI-supported clinical research. This resource allows the NCI to consolidate reporting, aggregate information and reduce redundant submissions. Information is submitted by clinical research administrators as designees of clinical investigators who conduct NCI-supported clinical research. The designees can electronically access the CTRP website to complete the initial trial registration. Subsequent to registration, four amendments and four study subject accrual updates occur per trial annually.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The estimated annualized burden hours are 38,500.

Estimated Annualized Burden Hours

Type of Respondents	Instrument	Number of Respondents	Number of Responses per Respondent	Average Time per Response (in hours)	Annual Burden Hours
Clinical Trials	Initial Registration	5,500	1	2	11,000
	Amendment	5,500	4	1	22,000
	Accrual Updates	5,500	4	15/60	5,500
Total		16,500			38,500

Dated: January 25, 2013

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Vivian Horovitch-Kelley

NCI Project Clearance Liaison

National Cancer Institute (NCI), National Institutes of Health (NIH)

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